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Fulbright & Jaworski, L.L.P.
600 Congress Avenue
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,928

Applicant(s)

HOLADAY ET AL.

Examiner

Dave T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 14-16, 18, -24, 27, 30-46 is/are pending in the application.
- 4a) Of the above claim(s) 16, 27 and 29-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 14, 15, 18-24 and 30-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claims 14, 15, 18-24 have been amended, claims 17, 25-26, and 28-29 have been canceled, claims 30-46 have been added by the amendment filed July 7, 2003.

Newly submitted claims 39-46 are now directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Originally filed claims were directed to an apparatus for electroporation, wherein, the apparatus, for example, comprises: walls defining a fluid flow path;

Electrodes disposed along sides of the fluid flow path, the electrodes being in electrical communication with a source of electrical energy, whereby biological particles moving along the fluid flow path to an electrical field; and

the apparatus being characterized by at least one of the walls defining the fluid flow path being elastically deformable and at least another one of the wall defining the fluid flow path being substantially rigid.

However, newly added claims 39-46 are directed to 1/ methods of incorporating a biologically active substance into cells in a continuous flow system, wherein numerous steps are recited so as to not necessarily be limited in any way the apparatuses as originally claimed (claims 39 and 43). Furthermore, the method as recited in claim 45 is drawn to a method of destroying any electroporation apparatus prior to re-use, wherein the method comprises just a functional language which does not clearly point out as to how the phrase "automatic breaking an electrode" is intended to mean. While claim 20 is drawn to a particular apparatus for electroporation, wherein the apparatus contains means for breaking the electrodes contained inside the apparatus so as to render the apparatus inoperative for

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a re-use, newly added claim 45 is in no way limited to the use of the apparatus of claim 20. Furthermore, each US filed application under 35 USC 121 is to have only one invention for examination. As evidenced by the newly added claims, these newly added claims embrace method(s) drawn to distinct goal(s) and materially distinct steps, and thus, render the as-filed application having multiple distinct inventions presently pending, which are not necessarily drawn to the same patentable invention. As such, these newly added claims have been withdrawn from further from further consideration by the examiner as being drawn to inventions distinct from the invention as originally claimed in this as-filed application.

Claims 16 and 27 remain withdrawn as drawn to non-elected species.

Only pending claims 14, 15, 18-24, 30-38, to which the following grounds of rejection remain and/or are applicable, are currently being examined.

The examiner notes that the written description rejection in the previous office action contains an typographical error with respect the inadvertent cut-and-paste of the phrase set forth on the bottom of page 3 of the previous office action. However, the examiner maintains that the written description rejection when read as a whole remains proper and does address the issues that were overcome by the amendment to the examined and pending claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is indefinite because the claim is drafted as a dependent claim which depends on itself, thereby being incomplete and does not set forth the complete metes and bounds of the claim.

Claims 31-33 are indefinite because the claims are dependent on a canceled claim. The metes and bounds of these dependent claims cannot be ascertained.

Claims 14, 15, 18-19, 22-24, 34-38 are rejected under 35 USC 103(a) as being unpatentable over Nicolau (WO 94/21117) taken with either Lichtenstein (US 4,370,983) or Meserol (US Pat NO. 6,090,617, which has a distinct inventive entity having a common inventor, i.e., Meserol).

The claims embrace a continuous electroporation apparatus comprising walls defining a fluid flow path, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles, and wherein the apparatus comprises a computer configured to:

- a. control charging of the electrodes, and
- b. establish a flow rate of the fluid flow path in accordance with a sample processing

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rate, e.g., a preprogrammed rate which corresponds to a processing rate of a blood sample from any integrated part or component of the apparatus such as separation or plasmaphoresis chamber.

Nicolau teaches the same on page 49, claim 21 cited on page 48, claims 1-7 cited on pages 42 and 43, pages 24 and 26, pages 35-40. With respect to the pump for moving the biological particles, Nicolau teaches the same on pages 21-22. The use of an electrical pulse from a pulse generator is disclosed on pages 25-26. The use and making of centrifugation and/or centrifugation container is described in page 32 and 33. Electrical controlled board and/or mechanical valves so as to link the chamber, pulse generator, the peristaltic pump, the blood cooling system are also disclosed on page 34 and page 40. More specifically and with respect to the concept of utilizing a computer to control the processing and flowing of a finalized purified blood sample product, Nicolau teaches on page 40:

For example, the flow electroporation chamber maybe connected to commercially available phasmaphoresis equipment by electronic or translational hardware or software. Optionally, a pinch-valve array and controller driven by a PC program can also be used to control the flow electroporation apparatus.

While neither the as-filed application nor the Nicolau reference provide any specific disclosure of any software and/or algorithm for the making of such computer, such making and/or using of computer-control software for monitoring and controlling of a medical

procedure is well-established in the prior art exemplified by Lichtenstein.

More specifically, Lichtenstein teaches the making and use of a computer as a main integral part of an electroporation or electrical infusion apparatus for use in infusing any pre-processed or processed blood sample into a patient at a flow rate according to a sample processing rate, e.g., entire disclosure, specifically column 6, lines 40-60, column 12, first full par., column 15, lines 15-41, column 23, lines 17-37, and column 24, first full par.

As such, it would have been obvious for one of ordinary skill in the art to employ a computer as an integral part of the electroporation apparatus of Nicolau, wherein the computer is made and utilized to control the operation and flowing of a blood sample in accordance with any parameter established in chamber and/or components operated within the apparatus. One of ordinary skill in the art would have been motivated to do so because not only Nicolau teaches that a computer can be optionally be set up in the electroporation apparatus to control the operation of the electroporation apparatus, Lichtenstein also teaches that it is well-known in the prior art to integrate a computer in any medical apparatus or procedure in order to enhance or precisely control all of the parameters set up for a particular procedure such as the flow rate of a sample blood fluid in accordance with the progress and/or variables produced or established in any medical apparatus. To the extent that the reference does not teach "continuous band electrodes", such limitation would have been obvious as a minor modification and matter of design choice. One with a high level of skill in the art would have been motivated to employ minor modification as a matter of design choice as long as the modifications are within the framework of the invention, particularly in the absence of evidence to the contrary.

Applicant argues on page 13 that Nicolau is a related application, thereby suggesting that Nicolau is not proper prior art used in the rejection, that Nicolau does not teach the limitation of the making and use of a computer as a main integral part of the claimed apparatus. However, the fact that Nicolau is identified as a related application in the specification does not preclude the reference from being properly used in a prior art rejection. Applicant's argument is also moot in view of the reasons set forth in the above stated rejection. Applicant's argument with respect to Figure 14 not being taught by Nicolau is also not persuasive because the presently pending claims are not claiming specifically the apparatus as presented in Figure 14, and to the extent that all of the limitations as recited in the claims are taught and suggested by the combined cited references, the rejection is applicable and proper.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 15, 18-24, 34-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of Meserol (US Pat No. 5,720,921, which has a different inventive entity wherein the common inventor is Meserol).

Although the conflicting claims are not identical, the examined claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims.

The examined claims and the claims of the patent when read in light of the disclosure of the patent are drawn to

a continuous electroporation chamber comprising walls defining a fluid flow path wherein the walls are partly elastically deformable and rigid, and electrodes disposed along sides of the path so as to emit pulses of electrical energy to the biological particles moving along the fluid flow path, and a cooling device, and wherein the chamber further comprises a electrical detection sensor so as to detect the flow rate of the pulses and/or biological particles, and wherein the chamber further comprises means that are connected to the electrodes employed in the claimed continuous electroporation chamber when said chamber is mounted to a support member for destroying said electrodes prior to the chamber being removed from the support chamber. The following portions of the specification of the patent are cited to support the above claimed invention: the cited Figure on the front page, column

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15 with respect to the electric field, column 20, lines 41-49 as to the cooling chamber, columns 20-21 with respect to the making of the electrodes, column 25 with respect to the making of a motor that can be used to destroy the electrodes after being used, columns 25 and 27, last paragraph as to the disclosure of the electrical board having appropriate algorithms in computer means for monitoring and controlling all of the mechanical means that are necessary to operate within the framework of the invention. In view of the metes and bounds of the claims of the reference patent that embrace the examined claims, particularly when read in light of the supported portions of the specification of the patent, one of ordinary skill in the art would have been motivated to have made the electroporation chamber as claimed because of the claims issued in the patent.

Applicant on page 15 asserts that no terminal disclaimer is needed since the current application is related to the cited patent by a claim of priority, such assertion is not found persuasive because the fact that the as-filed application claims priority to a US issued application does not preclude the presently pending claims from being subjected to an ODP ground of rejection.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER